

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG**
MDL No. 2738

THIS DOCUMENT RELATES TO ALL CASES

**PLAINTIFFS' STEERING COMMITTEE'S MOTION TO EXCLUDE THE
OPINIONS OF DEFENDANTS' TOXICOLOGY EXPERTS
BROOKE T. MOSSMAN, M.S., PH.D., KELLY S. TUTTLE, PH.D.,
AND H. NADIA MOORE, PH.D.**

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The Plaintiffs' Steering Committee ("PSC") respectfully submits this motion, pursuant to Fed. R. Evid. 104(a), 403, 702, and 703 to exclude the testimony of Defendants' toxicology experts Brooke T. Mossman, M.S., Ph.D., Kelly S. Tuttle, Ph.D., and H. Nadia Moore, Ph.D.

I. INTRODUCTION

Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. ("J&J") designated three toxicology experts on the issue of general causation: Dr. Brooke Taylor Mossman, Dr. Kelly Scribner Tuttle, and Dr. H. Nadia Moore. These experts were asked to determine if there is scientific evidence to demonstrate that talcum powder products present health risks to humans and whether it is biologically plausible that these products can migrate to the ovaries and cause ovarian cancer.

As a preliminary matter, it is important to clarify what "biologic plausibility" means within the Bradford Hill causation framework. Biologic plausibility does not require "proof of mechanism."¹ Rather, it requires only an assessment of the biologic evidence to see whether it "makes sense" that the association that is seen is indeed causal. The science makes biological sense when the association is credibly based

¹ See the PSC's Omnibus Brief at II (F), page 34.

on the understanding of the natural history of the disease or possible pathogenic mechanisms.²

Under *Daubert*,³ the burden is on J&J as the party offering these experts to demonstrate they are qualified and utilized reliable scientific methods to reach their opinions.⁴ Here, J&J failed to meet its burden for its designated toxicologists.

II. LEGAL STANDARD

The PSC incorporates the legal standards set forth in its Omnibus Brief Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation (“Omnibus Brief”) as supplemented herein.

III. OVERVIEW OF J&J’S DESIGNATED TOXICOLOGISTS

A. BROOKE T. MOSSMAN, M.S., PH.D.

1. Dr. Mossman’s Background

Dr. Mossman earned a Master of Science degree in physiology and biophysics from the University of Vermont in 1970. She then worked as a research assistant for

² Oleckno, W.A., *Epidemiology: Concepts and Methods* at 189 (2008). J&J’s experts attempt to convert this aspect of Bradford Hill from “plausibility” to “mechanical proof.” This is improper and unreliable. See, *Plaintiffs’ Steering Committee’s Memorandum of Law In Support of its Motion to Exclude the Opinions of Defendants’ Epidemiology Experts Karla Ballman, Ph.D., Christian Merlo, M.D., M.P.H., Gregory Diette, M.D., M.H.S., and Jonathan Borak, M.D., D.A.B.T.* at Section IV (B) (filed contemporaneous with this motion and referred hereinafter as “PSC’s Epidemiology Memorandum”).

³ *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

⁴ *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999).

the Institute of Environmental Medicine at New York University studying skin cancer and later earned a Ph.D. in cell biology from the University of Vermont in 1977.⁵ She testified that her training concerned lung pathology and disease associated with asbestos.⁶ Dr. Mossman is currently semi-retired and has some responsibilities through her office but is no longer paid by the University of Vermont.⁷ She currently serves as a Professor Emeritus of Pathology at the University of Vermont College of Medicine,⁸ and describes her professional title as a Professor of Pathology and Laboratory Medicine.⁹ Since partially retiring in 2014, Dr. Mossman has spent 50 to 75% of her time testifying in litigation and has testified approximately 65 times for Defendants in talcum powder litigation. In that regard, the vast majority of her income comes from her work as an expert witness.¹⁰

⁵ See Feb. 25, 2019 Expert Report of Brooke T. Mossman, M.S., Ph.D. (“Mossman Report”), attached as **Exhibit A**.

⁶ April 8, 2019 Deposition of Brooke T. Mossman, M.S., Ph.D. (“Mossman Dep.”) at 17:18-21, attached as **Exhibit B**.

⁷ *Id.* at 17:4-11.

⁸ Mossman Report at 2.

⁹ Mossman Dep. at 17:12-17.

¹⁰ *Id.* at 68:13-69:11. Dr. Mossman is listed as a “Key Scientist Supporting the Advancement of Sound Science Coalition TASSC,” which is an organization created by Philip Morris to fight smoking restrictions. *Id.* at 82:12-83:7, 83:23-85:21.

Dr. Mossman is not a medical doctor and has no formal education, background, training or experience regarding ovarian cancer.¹¹ She is not an epidemiologist, mineralogist, geologist, or materials analyst.¹² While her report indicates she has studied the roles of asbestos fibers in the induction of lung cancer, asbestosis and mesotheliomas for more than 40 years,¹³ she concedes when analyzing whether a sample is talc, asbestos, or talc with asbestos she leaves that to mineralologists.¹⁴ Similarly, she stated she would also defer to a mineralogist as to whether a sample is asbestos or asbestiform.¹⁵ She also admitted that she is not an expert in determining flexibility or rigidity of asbestos or cleavage fragments.¹⁶ Notably, she testified that levels of exposure to all types of asbestos in terms of human risk are outside of her area of expertise.¹⁷

Dr. Mossman admittedly does not have expertise or experience with the forms of asbestos and asbestiform talc at issue in this case. She conceded that she has not

¹¹ *Id.* at 17:22-18:14. Nonetheless, it is one of Dr. Mossman's opinions that the female reproductive tract has an "impenetrable barrier" and that ovaries are surrounded by a protective fibrous capsule which makes it impossible for talc to cause ovarian cancer. *Id.* at 493:13-495:6.

¹² *Id.* at 20:23-21:7.

¹³ Mossman Report at 2.

¹⁴ Mossman Dep. at 21:8-17.

¹⁵ *Id.*

¹⁶ *Id.* at 21:18-23.

¹⁷ *Id.* at 29:6-30:16.

researched tremolite asbestos, anthophyllite asbestos, or actinolite asbestos and has not researched the differences between tremolite asbestos and tremolite cleavage fragments or anthophyllite asbestos and anthophyllite cleavage fragments.¹⁸

Dr. Mossman has never studied cosmetic-grade talc and understands that cosmetic talc is the type of talc contained in Johnson's Baby Powder and Shower-to-Shower products, which are at issue in this case.¹⁹ Significantly, she has not studied the migration of talc.²⁰ She also does not know if there is a similar four-step process in the development of ovarian cancer to mesothelioma.²¹ In fact, Dr. Mossman has never studied the effect of asbestos and ovarian cancer.²² Similarly, she has never studied cosmetic grade talc, which she understands is the type of talc in J&J's talcum powder products at issue in this case²³ and admits that the grade of talc and type of asbestos they may contain affect how the products react with cells.²⁴

2. Summary of *Ipse Dixit* Opinions of Dr. Mossman

The crux of Dr. Mossman's opinions concern the topics of cosmetic talc mineralogy, toxicological effects to tissue from exposure to talc and asbestos,

¹⁸ *Id.* at 202:9-207:21.

¹⁹ *Id.* at 67:9-17.

²⁰ *Id.* at 210:24-211:5.

²¹ *Id.* at 45:13-16.

²² *Id.* at 165:17-166:17.

²³ *Id.* at 67:9-17.

²⁴ *Id.* at 397:10-22.

whether there is a scientifically plausible pathway for cosmetic talc particles to migrate to the ovary and fallopian tubes, and criticisms of the plaintiffs' experts, Drs. Saed and Zelikoff. Dr. Mossman believes that talc and asbestos are chemically, physically, and structurally distinct. She opines that, based on these differences, cosmetic talc particles are unlikely to reach or be retained at the site of development of ovarian cancer. Further, Dr. Mossman states that industrial and cosmetic talc do not have the potential for abnormal cell responses or play a role in cellular or molecular pathways integral for cancer development. She also opines that epidemiological and experimental studies assessing carcinogenic potential of asbestos support the concept that short fibers do not play a role in the induction of tumors. Moreover, she claims that experimental studies demonstrate no observed adverse effects from exposure to certain concentrations of asbestos. It is also her opinion that gene expression studies show that mesothelial tissue exhibits dose and time-related response to asbestos but not to talc, and that ovarian cells are more resistant to asbestos but show no response to talc. Finally, she criticizes Dr. Saed's research, claiming his 2019 study²⁵ is flawed and offers no support regarding causation. She is similarly critical of Dr. Zelikoff's opinions, asserting that her

²⁵ Fletcher, N. M., Harper, A. K., Memaj, I., Fan, R., Morris, R. T., & Saed, G. M. (2019). *Molecular Basis Supporting the Association of Talcum Powder Use With Increased Risk of Ovarian Cancer*. *Reproductive Sciences*, attached as **Exhibit C**.

opinions are not supported by peer-reviewed literature and basic tenants of toxicology and carcinogenicity.

B. KELLY S. TUTTLE, PH.D.

1. Dr. Tuttle's Background

Dr. Tuttle is a toxicologist and industrial hygienist at the consulting firm Center for Toxicology and Environmental Health, LLC (“CTEH”). She has a Bachelor of Science degree in Veterinary Science and a Ph.D. in Toxicology. Dr. Tuttle was retained by J&J in October/November of 2018 to opine regarding the association between talcum powder products and ovarian cancer and to critique the methodologies employed by the plaintiffs’ experts. As addressed below, Dr. Tuttle plagiarized significant portions of her report, claimed expertise in areas where she is lacking, and failed to follow scientifically accepted methodology – particularly neglecting to perform a thorough scientific literature review. These errors preclude her from providing reliable opinions in this case.

2. Summary of *Ipse Dixit* Opinions of Dr. Tuttle

Dr. Tuttle provides a thinly veiled conclusion that the scientific evidence put forth by the plaintiffs’ experts does not meet the methodological standards and criteria for causality. Moreover, according to Dr. Tuttle, the evidence regarding causation, the presence of heavy metals, asbestos, fibrous talc, fragrance chemicals, and toxicity information do not prove that perineal or inhalation

exposure to talcum powder significantly increases an individual's risk of ovarian cancer.²⁶

C. H. NADIA MOORE, PH.D.

1. Dr. Moore's Background²⁷

Dr. Moore received her Ph.D. in toxicology from the University of Washington in 2008 and presently works for the consulting group Veritox, Inc.²⁸ She has offered expert testimony in one prior matter, a case involving a dispute between the City of Oakland, California and a developer over health hazards posed by coal dust.²⁹ Dr. Moore previously described her expertise as follows:

Q. And do you have a specialty within the field of toxicology?

²⁶ See Feb. 25, 2019 Expert Report of Dr. Kelly Scribner Tuttle ("Tuttle Report") at 71, attached as **Exhibit D**.

²⁷ The evening prior to Dr. Moore's deposition, J&J served a new reliance list which included 85 new references that Dr. Moore relied upon in forming her opinions; "Fragrance Ingredient Concentration – Baby Powder" charts that were created by Dr. Moore in support of her opinions; and analyses of heavy metal test results relied on by plaintiffs' experts Drs. Cook and Krekeler, which formed the basis of Dr. Moore's opinions, see attached as **Exhibit E**. These materials were not provided in sufficient time for either the PSC or its experts to review them. The PSC sought additional time to depose Dr. Moore. The Special Master denied this request. The PSC plans to appeal the decision. The failure to timely disclose these reliance materials prevented the PSC from examining Dr. Moore on the full bases of her opinions.

²⁸ Feb. 26, 2019 Expert Report of H. Nadia Moore, Ph.D., DABT, ERT ("Moore Report") at 3, attached as **Exhibit F**.

²⁹ See *Oakland Bulk and Oversized Terminal, LLC vs. City of Oakland*, Case No. 3:16-cv-07014-VC (N.D. Ca.).

A. I've done a lot of inhalation toxicology work. In toxicology you can look at different ways people are exposed. So you might eat something or you might breathe something. So I focus on what people breathe.³⁰

Dr. Moore's first involvement with talcum powder began in the summer of 2017 in connection with a presentation at the American Conference Institute's "Sixth Annual Toxic Tort Environmental Litigation" meeting. In preparation for this presentation, she was asked to perform a causation analysis of talc and ovarian cancer and understand how it differed from asbestos and mesothelioma.³¹ Prior to the presentation, Dr. Moore admits that she had no experience with talcum powder or ovarian cancer "[b]eyond reading the occasional article...."³² None of the projects that she worked on in her previous career as a research scientist involved talc, asbestos, or perineal exposure.³³

Despite this limited background, Dr. Moore states that she was "asked to provide an expert opinion as a toxicologist regarding alleged adverse health effects from exposure to Johnson's Baby Powder and Shower-to-Shower."³⁴ Dr. Moore did not perform independent testing in her expert work, but rather conducted a "review

³⁰ See *Oakland Bulk*, Moore Trial Testimony at 573, attached as **Exhibit G**.

³¹ Deposition of H. Nadia Moore, PhD, dated April 4, 2019 ("Moore Dep.") at 110:1-114:21, attached as **Exhibit G**.

³² *Id.* at 33:1-34:9.

³³ *Id.* at 55:5-58:20.

³⁴ Moore Report at 1.

and analysis of published literature on the effects of asbestos, talc, cobalt, chromium, nickel and fragrance ingredients....”³⁵

So, my job, as I saw it -- my task was to evaluate the scientific literature that was related to this issue. As part of that, I identified a lot of articles that I considered as part of my opinion, and that's what's reflected in this.³⁶

She carried out this “job,” she explained, “through searching, PubMed searching as well as Google searching, evaluating articles that came from those searches, and then looking at those references of those articles, pulling another iteration of that.”³⁷

2. Summary of *Ipse Dixit* Opinions of Dr. Moore

Dr. Moore conducted a weight of evidence analysis and principally opines that the “scientific literature does not support a causal relationship between perineal talc and ovarian cancer.”³⁸ Dr. Moore offers secondary opinions that potential components of talcum powder products – asbestos, fibrous talc, chromium, cobalt, nickel, and various fragrance ingredients – do not cause ovarian cancer in humans. Finally, Dr. Moore offers critiques of several of the plaintiffs’ experts: Drs. Carson (medical toxicology), Crowley (pharmaceutical and cosmetic chemistry), Longo (analysis of samples for the presence of asbestos and fibrous talc), Plunkett

³⁵ *Id.* at 5.

³⁶ Moore Dep. at 40:20-25.

³⁷ *Id.* at 41:4-8.

³⁸ Moore Report at 1.

(toxicology/pharmacology/regulatory), Saed (cancer biology), and Zelikoff (toxicology), “because they all touch on my field of toxicology.”³⁹

IV. ARGUMENT

As set forth in the PSC’s *Omnibus Brief*, to satisfy Fed. R. Evid. 702 and *Daubert*, an expert witness must satisfy three (3) requirements: (1) the expert must be *qualified*, (2) the expert’s opinions must be *reliable* and based on a proper methodology, and (3) the expert’s testimony must be relevant and *fit* the facts of the case.⁴⁰ The opinions of J&J’s toxicology experts fail to clear each of these hurdles and should be excluded under *Daubert* for several reasons.

A. DR. MOSSMAN’S OPINIONS SHOULD BE EXCLUDED

1. Dr. Mossman’s Opinions Are Not Reliable

Dr. Mossman’s opinions are not reliable. “Under the Federal Rules of Evidence, a trial judge acts as a ‘gatekeeper’ to ensure that ‘any and all expert testimony or evidence is not only relevant, but also *reliable*.’” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). To be reliable, an expert’s opinions must be based on scientifically reputable methods and procedures that can be validated and tested

³⁹ *Id.*

⁴⁰ *Kars 4 Kids, Inc. v. Am. Can!*, No. 314CV7770PGSDEA, 2019 WL 1755912, at *1 (D.N.J. Apr. 18, 2019) (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008); *accord JVI, Inc. v. Truckform Inc.*, No. CIV. 11-6218 FLW, 2012 WL 6708169, at *4 (D.N.J. Dec. 26, 2012)).

as opposed to subjective beliefs and unsupported conclusions. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145–46 (3d Cir. 2000) (holding that an expert's *ipse dixit* does not withstand *Daubert*'s scrutiny). Dr. Mossman's opinions do not meet this standard and instead are merely unsupported *ipse dixit* positions.

Dr. Mossman did not arrive at her conclusions “in a scientifically sound and methodologically reliable fashion.” *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). An expert must employ “the same level of intellectual rigor” that they would use outside of the courtroom in forming the opinions that they intend to offer in litigation. *In re Johnson & Johnson Derivative Litig.*, 900 F. Supp. 2d 467, 493 (D.N.J. 2012) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999); *Betterbox Communications Ltd. v. BB Technologies, Inc.*, 300 F.3d 325, 329 (3d Cir. 2002)).

Dr. Mossman says that she arrived at her opinions in this case “the same as [she] would have done” in reviewing a scientific paper for a peer-reviewed journal and by looking at all of the “peer-reviewed literature on the topic.”⁴¹ But, a closer analysis of her testimony reveals that is not what she actually *did*. Instead, the deposition testimony of Dr. Mossman reveals a classic example of an expert witness veering far out of their lane and engaging in cherry-picking along the way.

⁴¹ Mossman Dep. at 436:11-437:5.

Dr. Mossman, a pathology and laboratory medicine expert, intends to offer the opinion that the *epidemiological studies* do not show a statistically significant increased risk of ovarian cancer from genital talc use.⁴² Dr. Mossman primarily bases her opinions on her review of the epidemiology.⁴³ However, she is not an epidemiologist and she admitted that she was not going to get into the “shortcomings” of the selected studies which she relied on.⁴⁴ In fact, she conceded that it has not been her professional role to question or critique studies as to their strengths or weaknesses in terms of their positive or negative features – much less determine their impact.⁴⁵

⁴² *Id.* at 130:19-24, 136:10-140:1.

⁴³ *Id.* at 139:13-140:1

⁴⁴ *Id.* at 142:4-22.

⁴⁵ *Id.* at 154:6-24.

a. Methodological Flaw: Improper Study Evaluation

Rather than reviewing the totality of the epidemiologic evidence, Dr. Mossman self-selected and reviewed a subgroup of fourteen to twenty case-control studies which she claims did not show a statistically significant increased risk or dose-response relationship.^{46,47}

First, and as demonstrated in Section IV (A) (3) of PSC's *Epidemiology Memorandum*, "significance testing" to show association or consistency of association is an improper methodology which has been rejected in both the epidemiology and statistical communities.⁴⁸ While the PSC refers to that motion for a more complete discussion of that issue, it points out the recent statement of the American Statistical Association (ASA). The ASA position was summarized in several editorials which accompanies 43 articles in its peer-reviewed journal, *The American Statistician* (March 2019), including one by Amarhein *et al.* who

⁴⁶ *Id.* at 149:17-151:5. There are 35 observational studies of talcum powder and ovarian cancer: 31 case-control studies, 1 pooled case-control studies, and 3 cohort studies. The overwhelming majority (n=34) of these studies, irrespective of study design, found a positive association (i.e., a hazard ratio > 1), with most showing an association in the range of 1.1-1.7 representing a 10-70% increased risk of ovarian cancer with talcum powder use. In a majority of the published studies (n=19), the positive association reported was statistically significant to a p=.05. See PSC's *Epidemiology Memorandum* at Section IV(B)(1). From her report and deposition, it does not appear Dr. Mossman considered these statistically significant positive studies or the studies demonstrating dose response.

⁴⁷ Significance testing is an improper methodology. *Id.* at Section IV(A)(3).

⁴⁸ *Id.*

described what Dr. Mossman engaged in here as a “pervasive problem” which “must stop”:

PERVASIVE PROBLEM:

Let’s be clear about what must stop: We should never conclude that there is ‘no difference’ or no association just because a p value is larger than a threshold of .05 or equivalently because a confidence interval includes zero. *Neither should we conclude that two studies conflict because one has a statistically significant result and another did not. These errors waste research efforts and misinform policy decisions.*⁴⁹

Beyond this article, the ASA has issued a number of similar statements directed at scientists like Dr. Mossman, who are neither epidemiologists nor statisticians by training.⁵⁰

Second, and as further set forth in the *PSC’s Epidemiology Memorandum* at section IV(B), Dr. Mossman and other J&J experts mischaracterize several relevant aspects of the Bradford Hill Guidelines on assessing causation. In addition to recasting “biologic plausibility” as requiring “biologic proof” and not “plausibility,” Dr. Mossman and others recast the “biologic gradient” or “dose response” element in a way that is not supported by Professor Hill or any epidemiologist outside of this litigation. As Hill and others make clear, this is evidence which is “difficult to

⁴⁹ Amrhein, et al., *Retire Statistical Significance*, 567 Nature 305, 306 (2019), see attached as **Exhibit I**.

⁵⁰ See the *PSC’s Epidemiology Memorandum* at n. 50.

secure” so any evidence of any type on this issue should be sought.⁵¹ Dr. Mossman and other experts here strive to convert Hill’s dose-response analysis from any “evidence” of dose response into statistically significant and consistent results across available epidemiologic studies – a standard not compatible with Hills’ own analysis.

In the course of Dr. Mossman’s limited review of the observational studies on talcum powder products and ovarian cancer, Dr. Mossman represented that she reviewed the meta-analyses performed over the last four decades. With the exception of the Penninkilampi study, she testified that the talc meta-analyses performed to date did not show a statistically significant increased risk of ovarian cancer.⁵² Dr. Mossman here is patently wrong. Numerous published and unpublished meta-analyses have been conducted by authors in the fields of epidemiology, statistics, gynecology and public health addressing talcum powder products and ovarian cancer, all of which demonstrate a consistent and statistically significant 25% to 45% increased risk of ovarian cancer.⁵³ These demonstrably incorrect statements by Dr. Mossman, as well as the other examples listed below, are illustrative of her

⁵¹ Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc’y Med. 295, 298 (1965) (emphasis added), attached as **Exhibit J**.

⁵² Mossman Dep. at 183:12-185:7.

⁵³ See the PSC’s *Epidemiology Memorandum* at n. 21.

willingness to reach conclusions based on her superficial and incomplete analysis of the data:

- Dr. Mossman failed to address the totality of the epidemiologic literature, including the strengths and weaknesses of relevant studies.⁵⁴
- Dr. Mossman used improper “significance testing,” a methodology that is rejected in both the statistical and epidemiological community.⁵⁵
- Dr. Mossman failed to recognize that causal relationships exist below 2.0.⁵⁶
- Dr. Mossman failed to acknowledge accepted metrics, of frequency and duration, for measuring dose-response.⁵⁷

Another harbinger of Dr. Mossman’s unreliable opinions is based on her mistaken criticisms of plaintiffs’ experts regarding their causation opinions. For instance, Dr. Mossman claims Dr. Saed failed to disclose the source of funding for his talc research. A cursory review of his 2019 publication, however, demonstrates that Dr. Mossman is wrong and that the publication clearly discloses the funding for his study.⁵⁸ Dr. Mossman also makes unfounded claims that Dr. Saed’s motivation for research regarding talc was to advance litigation rather than scientific knowledge.

⁵⁴ Mossman Dep. *Id.* at 18:23-19:6.

⁵⁵ *Id.* at 141:21-142:3. See also the PSC’s *Epidemiology Memorandum* at Section IV(A)(3).

⁵⁶ *Id.* at 141:21-142:3.

⁵⁷ *Id.* at 144:11-145:21.

⁵⁸ Fletcher (2019).

Her contention is misplaced, however, as the vast majority of Dr. Saed's research in this area was conducted prior to his involvement in this litigation. Similarly, Dr. Mossman's criticisms of Dr. Zelikoff are without merit. Dr. Mossman claims Dr. Zelikoff's conclusions are not supported by peer-reviewed scientific literature. A cursory review of her report, however, shows that it is replete with citations to such literature. For example, in her discussion of migration, Dr. Zelikoff cites to both animal and human studies.⁵⁹ In reaching her causation opinion, Dr. Zelikoff provides copious scientific support and states:

in sum, inflammation is a primary mediator of ovarian cancer. *As the scientific studies outlined above demonstrate*, talcum powder product cause inflammation that can result in an elevation of biomarkers; changes in cell signaling; activation of chemokines and cytokines; changes in the oxidative environment; gene alteration and/or mutations; inhibition of apoptosis and induces neoplastic transformation and proliferations (*i.e.* cancer). This talcum powder-indicted inflammatory cascade provides significant biologic and toxicologic support for a conclusion that talcum powder products can cause ovarian cancer.⁶⁰

⁵⁹ See Nov. 16, 2018 Expert Report of Judith Zelikoff, Ph.D., attached as **Exhibit K**, at 11-16 (citing Keskin 2009, Henderson 1986, Wehner 1996, Wright 1995, Egli 1961, DeBoer 1972, Venter 1979, FDA correspondence (dated April 1, 2014), and an internal Luzenac (now Imerys) document).

⁶⁰ *Id.* at 20-26 (emphasis added).

In this portion of her report, Dr. Zelikoff cites to more than thirty peer-reviewed, scientific publications, including Dr. Mossman's 2009 study,⁶¹ in support of her causation opinion.⁶²

Dr. Mossman's meritless criticisms of Dr. Saed and Zelikoff is further evidence that her opinions are without foundation and are therefore unreliable.

b. Methodological Flaw: Cherry-Picked Biologic Data from the Scientific Literature and her own Research

In forming her opinions, Dr. Mossman intentionally chose not to investigate and failed to consider the totality of the biologic evidence relevant to the talc-ovarian cancer question. In addition to failing to consider whole biologic studies, she cherry-picked data favorable to her opinions and ignored unfavorable data that did not. Indeed, she goes so far as to ignore data from her own studies which conflict with her current litigation opinions.

For example, she did not consider any of the data from animal experiments since 2006.⁶³ Furthermore, she never conducted any experiments on cosmetic talc

⁶¹ Dr. Mossman was a co-author of the Shukla 2009 study. *See infra* n. 74.

⁶² *Id.*

⁶³ Mossman Dep. at 151:23-152:19. Dr. Mossman has not considered any animal studies beyond what was contained in the 2010 IARC Monograph (data/study cut-off in 2006) and conceded that most of those studies had occurred well before the publication of the monograph in 2010.

and ovarian cancer, asbestos/asbestiform and ovarian cancer, fibrous talc and ovarian cancer, heavy metals and ovarian cancer or fragrances and ovarian cancer.⁶⁴

Dr. Mossman testified that she did not know what types of asbestos have been found in J&J's talcum powder products and actually assumed (incorrectly) that no asbestos has been found.⁶⁵ It is concerning that she made assumptions about what constituents are contained in talcum powder products while ignoring testing that was performed on J&J's historical talcum powder products which revealed the presence of asbestos and fibrous talc.⁶⁶ Similarly, while she was aware of Dr. Zelikoff's report regarding carcinogenic heavy metals contained in J&J's talcum powder products, she failed to review that testing as the reports are not listed on her reference materials.⁶⁷ Likewise, Dr. Crowley's report regarding the presence of toxic fragrances is omitted from her references.⁶⁸ Even more significantly, Dr. Mossman turned a blind eye to internal J&J and Imerys company documents regarding the types of asbestos found in the companies' own testing of the products.⁶⁹ She also

⁶⁴ *Id.* at 164:17-21, 166:2-7, 167:21-24, 169:6-8.

⁶⁵ *Id.* at 179:21-180:3. Dr. Mossman had not even seen the report of Drs. Longo and Rigler, which identified asbestos and fibrous talc in J&J's talcum powder products. *Id.* at 180:5-8.

⁶⁶ *Id.* at 179:21-180:8;199:22-200:3.

⁶⁷ *Id.* at 190:11-22. *See also* Mossman Report at Exhibit B, Key References and Reliance Materials.

⁶⁸ *Id.*

⁶⁹ Mossman Dep. at 181:23-182:9, 199:22-200:3.

failed to consider Taher 2018 or Health Canada’s Draft Assessment which found a causal role for perineal talcum powder products and ovarian cancer.⁷⁰ Thus, Dr. Mossman cherry-picked only the studies and materials that she thought would support her opinions and chose not to look at a variety of relevant evidence (*e.g.*, other studies, tests, and Defendants’ own internal company documents) which might be contrary to her conclusions and which should have been considered as part of analyzing the totality of the evidence.

To be clear, Dr. Mossman cherry-picked only the studies and materials that she thought would support her opinions and chose not to look at a variety of relevant evidence (*e.g.*, other studies, tests, and Defendants’ own internal company documents) which might be contrary to her conclusions and which should have been considered as part of analyzing the totality of the evidence. One must also question whether she actually reviewed the 2012 IARC Monograph 100c, which addresses asbestos and fibrous talc as a carcinogen. In her expert report, Dr. Mossman incorrectly claims that “[f]ibrous talcs not containing asbestos fibers have not been classified as human carcinogens,” citing IARC Monograph 93 (2010) at page 412.⁷¹

⁷⁰ *Id.* at 222:19-223:7; 228:15-229:6; 316:1-7.

⁷¹ See Mossman Report at 23 and 35.

However, IARC Monograph 100c (2012) indicates Group I carcinogenicity applies to both asbestos and talc containing asbestiform fibers (e.g. fibrous talc).^{72, 73}

Striking to the opinions offered and methodology performed by Dr. Mossman is the fact that in addition to cherry-picking study data from studies and research performed by others is the fact that Dr. Mossman cherry-picked favorable data (ignoring data to the contrary) from her own research and study findings to support her conclusions in this case.⁷⁴

To illustrate, Dr. Mossman claimed that talc produced “less striking increases in gene expression” as compared to asbestos yet she failed to report the following favorable findings:

- She failed to state talc showed several statistically significant changes to genes in cancer pathways.⁷⁵

⁷² IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, *Arsenic, Metals, Fibres, and Dusts*, Vol. 100C: A review of Human Carcinogens, 2012, attached as **Exhibit L**, concludes that all forms of asbestos are carcinogenic to humans (Group 1)). The document states “[t]he conclusions reached in this *Monograph* about asbestos and its carcinogenic risk apply to these six types of fibres wherever they are found, and that includes talc containing asbestiform fibres.” *Id.* at 219. As the Monograph goes on to make even more clear, talc formed in an asbestiform habit is included in this description. *Id.* at 230. And, IARC recognized perineal application of talcum powders is as a primary source of exposure to the human population of talc with asbestiform fibers, including asbestos. *Id.* At 232.

⁷³ Fibrous talc is a synonym for talc formed in an asbestiform habit.

⁷⁴ Shukla, A. et al. 2009. Alterations in gene expression in human mesothelial cells correlate with mineral pathogenicity. Am.J.Respir.Cell Mol.Biol. 41(1):114-123 (co-authored by Dr. Mossman), attached as **Exhibit M**.

⁷⁵ See Mossman Report at 24.

- Her study revealed 30 gene expression changes to peritoneal mesothelioma cells at higher concentrations of non-fibrous talc.⁷⁶
- She admitted that AFT3 is induced by a variety of stress and inflammatory conditions.⁷⁷
- She conceded that IL8 is a cytokine produced by lymphocytes during inflammation or to mediate inflammation.⁷⁸

The omissions described above are material and go to the heart of the lack of reliability of her opinions in this case. They explain and support an important element of biologic plausibility. Importantly, these findings, which were not reported by Dr. Mossman, support the proposition that talcum powder products cause an inflammatory response. An inflammatory response in ovarian cancer cells provides a biologically plausible explanation for the increased risk for the association seen in the epidemiology studies. This is one more line of evidence that would support a causal inference between talcum powder products and ovarian cancer.

c. Flawed Methodology: Migration

Dr. Mossman testified during her deposition and opines that there is no “proof” that talcum powder products migrate to the ovaries. Putting aside her improper conversion of “plausibility” to “proof,” a concept inconsistent with the Hill

⁷⁶ Mossman Dep. at 46:4-10.

⁷⁷ *Id.* at 59:13-22.

⁷⁸ *Id.* at 60:17-21.

analysis of biologic plausibility, Dr. Mossman has not familiarized herself with the literature on this topic. While Dr. Mossman may have been minimally qualified to address the gynecologic question of migration, she failed here to sufficiently research and inform herself on the subject. When questioned as to whether there is a scientifically plausible pathway for cosmetic talc to migrate to the ovaries or fallopian tubes, she admitted she has not studied the topic.⁷⁹

Despite her unfamiliarity with the literature, her report describes “barriers” to particulates in the female reproductive tract. She also states that “it is difficult to conceive of a route whereby talc” after perineal dusting would reach the ovaries and persist in sufficient doses to cause ovarian cancer.⁸⁰ Dr. Mossman makes this assertion without consideration of a large body of relevant scientific literature relied upon by the plaintiffs’ experts, which demonstrate a biologic mechanism whereby particulates can ascend the female reproductive tract.⁸¹

Moreover, and as set forth above, she applies an incorrect standard to determine biologic plausibility, stating that there is no demonstrated “proof” of

⁷⁹ *Id.* at 210:24-211:5. She also failed to consider the FDA’s position on migration as set forth in communications as recent as 2014 which state “the potential for talc to migrate from the perineum and vagina to the peritoneal cavity is “indisputable.” *Id.* at 349:12-350:22.

⁸⁰ Mossman Report at 11.

⁸¹ See *Id.* at 10-11 and generally Key References and Reliance Materials B to Mossman Report (omits migrations studies cited by plaintiffs’ experts).

migration.⁸² She dismissed a number of peer-reviewed studies which indicated and support the plausibility of talc to migrate, as she does not believe these studies *prove* to her satisfaction that talc migrates.⁸³ Contrary to Dr. Mossman's unsupported opinions, there is clear biologically plausible evidence here that talc can migrate. In other words, it does make biologic sense that the association seen in the observational studies over four decades is indeed a causal one.

Compounding her error, is her failure to review the totality of the literature and educate herself on the relevant research in this area. These omissions and errors make her opinions unreliable and should disqualify her from rendering an opinion on migration. “An expert’s opinion may be unreliable” where, as here, the expert “fails to account for contrary scientific literature” or ignores key evidence “and instead ‘selectively choose his support from the scientific landscape’” and fails to take into account matters that are unfavorable or do not support his opinions. *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 676 (S.D.W. Va. 2014) (quoting *In re Rezulin Prod. Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005)).

“[T]he reliability of an expert’s opinion should be seriously questioned when it is shown that the expert formed his or her opinion” with “merely cherry-picked evidence favorable to that opinion.” *In re Seroquel Prods. Liab. Litig.*, 2009 WL

⁸² Mossman Dep. at 229:7-230:19.

⁸³ *Id.* at 315:20-344:4.

3806434, at *5 (M.D. Fla. June 18, 2009).⁸⁴ Furthermore, it is a major reliability “red flag” where, as here, an expert has been shielded from sufficient information about the case or whose objectivity is clouded by their background and bias. *See Dow v. Rheem Mfg. Co.*, 527 F. App'x 434, 437 (6th Cir. 2013).⁸⁵

As set forth above, Dr. Mossman made serious methodological errors in reaching her opinions. Among other things, she applied improper methodology in

⁸⁴ See *In re Neurontin Mktg. & Sales Practices Litig.*, 04-CV-10739-PBS, 2011 WL 3852254, at *34 (D. Mass. Aug. 31, 2011), aff'd, 712 F.3d 21 (1st Cir. 2013) (excluding expert's testimony where it was found that the expert “reache[d] his opinion by first identifying his conclusion . . . and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion.” (citing *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007)); *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 858 (E.D.N.C. 2015); see also *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449 (E.D. Pa. 2014) (finding expert's opinion not reliable or scientifically sound because the expert failed to account adequately for contrary evidence (citing *In re Avandia Mktg.*, No. 2007-MD-1871, 2011 U.S. Dist. LEXIS 479, at *9 (E.D. Pa. 2011))).

⁸⁵ Dr. Mossman's failure to review any of Defendants' internal company documents in forming her opinions is particularly important because Dr. Mossman actually worked with Dr. Alfred P. Wehner who was a J&J and Cosmetic Fragrance Toiletries Association (CFTA, now PCPC) consultant for many decades, beginning in the 1970s when J&J did testing that confirmed the presence of asbestos in its talc products and began thoroughly discussing the link between perineal talc exposure and ovarian cancer. *See, e.g.*, Exhibit 5 from the Deposition of Brooke T. Mossman, PhD., dated April 8, 2019, attached as **Exhibit N**. As a result of her extensive work and connection with Dr. Wehner, it is inconceivable that Dr. Mossman would not know that J&J's own internal documents would be inconsistent with her opinions and conclusions in this case.

selecting and assessing the relevant epidemiology, including improper significance testing and ignoring evidence that was contrary to her opinions in this case.

Specifically, with respect to the in vitro studies, she ignored studies that did not support her opinion and as previously discussed, disregarded results in her own studies that do not support her current litigation opinions. Finally, in addressing migration, a topic in which she has minimal qualifications, she applied the wrong standard for biologic plausibility and ignored studies of scientists and regulatory agencies far more qualified than her who concluded that migration is indeed plausible.⁸⁶

Dr. Mossman's *ipse dixit* opinions are not "based on the 'methods and procedures of science'" and are instead based on her "subjective belief" and "unsupported speculation" which she does not "have 'good grounds' for." *Kars 4 Kids, Inc.*, 2019 WL 1755912, at *1 (quoting *Pineda*, 520 F.3d at 742).

The law requires that the "process or technique the expert used in formulating the opinion" must be "reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741–42 (3d Cir. 1994)). Dr. Mossman's opinions fail to satisfy this requirement. Even

⁸⁶ See Draft Screening Assessment, Talc, Environment and Climate Change Canada, Health Canada, December 2018, attached as **Exhibit O** and FDA Response to Samuel S. Epstein, M.D.'s Citizen Petitions, dated April 1, 2014, attached as **Exhibit P**.

setting aside the reliability issue, Dr. Mossman could not testify that her opinions were rendered with any degree of scientific certainty.⁸⁷

For the above reasons, Dr. Mossman's opinions should be excluded as unreliable.

B. DR. TUTTLE'S OPINIONS SHOULD BE EXCLUDED

1. Dr. Tuttle Is Not Qualified to Offer General Causation Opinions in this Case

Dr. Tuttle's general causation opinions extend well beyond her limited training and experience. Dr. Tuttle demonstrated in her report and deposition that she does not understand and cannot explain basic scientific concepts, cannot provide support for her *ipse dixit* opinions, and will be unable to address key scientific issues in this case. A thorough review of her report also reveals that she plagiarized significant portions in an effort to claim the expertise she lacks. Here, Dr. Tuttle's testimony and opinions will only serve to confuse and not assist the trier of fact. Accordingly, Dr. Tuttle's testimony and opinions should be excluded in full.

"While the background, education, and training may provide an expert with general knowledge to testify about [a topic], more specific knowledge is required to support more specific opinions." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d

⁸⁷ See *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d at 751; *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 150 (3d Cir. 1999); *Johnson v. SmithKline Beecham Corp.*, 55 F. Supp. 3d 603, 613 (E.D. Pa. 2014).

316, 322 (3d Cir. 2003). “[A]t a minimum, a proffered expert witness must possess skill or knowledge greater than the average layman.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (quotations and citation omitted). Additionally, “the expert’s opinion must be based on the methods and procedures of science rather than on subjective belief or supported speculation. . . .” *Calhoun*, 350 F.3d at 321.⁸⁸ Dr. Tuttle lacks the necessary background, education, and training to provide reliable causation opinions in this case.

Dr. Tuttle is a toxicologist and industrial hygienist. She is not an epidemiologist, has never taken a course which required an epidemiology textbook, and has never reviewed the leading textbook on epidemiology.⁸⁹ Dr. Tuttle’s report, however, includes twelve pages focused on epidemiological information and supposed analysis.⁹⁰ Dr. Tuttle’s testimony revealed her inexperience in this field, and demonstrated that she lacks a basic understanding of epidemiologic concepts.

For example, despite using the term “confounding” throughout her expert report as a basis for her opinions,⁹¹ she is unable to define it:

Any definition I would offer right now would be, you know, my interpretation or my kind of summation without

⁸⁸ See also *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003).

⁸⁹ April 11, 2019 Deposition of Kelly Scribner Tuttle, Ph.D. (“Tuttle Dep.”) at 80:14-85:16, attached as **Exhibit Q**.

⁹⁰ See Tuttle Report at 19-29, 35, 36.

⁹¹ See *id.* at 6, 11, 14, 18, 20-26.

having, you know, what I have in my report right now in front of me, and I don't want to misquote what the scientific definition of confounding is.⁹²

Dr. Tuttle also lacks relevant expertise in conducting a Bradford Hill analysis.

While she testified she uses “the Hill criteria throughout [her] work as a toxicologist” and uses it “regularly in assessing the scientific literature in the body of science,” she admitted she has never used it to assess the safety of a manufactured product.⁹³

Indeed, none of Dr. Tuttle’s unrelated publications (and none related to the issues in this case) addresses a Bradford Hill analysis.

Because Dr. Tuttle lacks her own expertise and knowledge in the relevant area, she plagiarized large segments of her report from prior reports submitted by a more senior toxicologist at her company in unrelated litigation, including more than

⁹² Tuttle Dep. at 154:20-156:11; *see also id.* at 152:13-154:1; 154:20-155:8; 156:1-157:15.

⁹³ *Id.* at 27:5-11. *Casarett and Doull's* explains the Bradford Hill viewpoints were largely developed for interpreting a body of epidemiology data, but are also relevant to toxicology. Klaasen, C.D. “General Principles of Toxicology.” *Casarett and Doull's toxicology: The Basic science of poisons.* 8th ed., New York: McGraw-Hill, 2013, p. 16, see attached as **Exhibit R.**

five pages of her “Scientific Causation Methodology” section.^{94,95} Additionally, and notwithstanding her stated expertise as a toxicologist, Dr. Tuttle also plagiarized a substantial portion of the “Toxicological Principles” section of her report.⁹⁶

As discussed below, this overt plagiarism from a more senior scientist explains, at least in part, why Dr. Tuttle was not able to testify completely on the methodology and content contained in her own report. Dr. Tuttle had to plagiarize because she lacks the requisite knowledge of basic epidemiology, general causation, and toxicological concepts, rendering her opinions unreliable.^{97, 98}

⁹⁴ Compare “5.0 Scientific Causation Methodology” (Tuttle Report at 4-6) with April 1, 2012, Expert Report of John A. Kind, Ph.D., *Tammie White v. Florida Marine Transportation, Inc.*, Case No. 2:11-cv-01161, United States District Court for the Eastern District of Louisiana and September 16, 2016, Expert Report of John Kind, Ph.D., CIH, *Kelly G. Watson v. BNSF Railway Company*, Case No. AC 17-0694, Montana Supreme Court.

⁹⁵ Demonstrative comparing Dr. Tuttle’s Expert Report and the 2012 and 2016 Expert Reports of Dr. Kind (“Kind 2012” and “Kind 2016”) with plagiarized sections highlighted, attached as **Exhibit S**.

⁹⁶ See Tuttle Report at 7-17; demonstrative, Exhibit S.

⁹⁷ *Calhoun*, 350 F.3d at 321 (“...the testimony must be reliable....‘the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation...’”) (citations omitted).

⁹⁸ While plagiarism alone generally will not disqualify an expert from testifying and is typically a matter of cross exam, the plagiarism engaged in by Dr. Tuttle here is so pervasive that it is clear it was not conducted as a matter of convenience or uniformity in citing general principles of epidemiology and toxicology. Instead, her testimony demonstrates that she engaged in plagiarism because she lacked the qualifications and experience in, and cannot demonstrate even a minimal understanding of, those subjects she plagiarized.

2. Dr. Tuttle Fails to Employ a Reliable Methodology Used in Her Own Field of Toxicology

Dr. Tuttle failed to employ generally accepted methodology in rendering her toxicology opinions. She claims an ability to perform a risk assessment,⁹⁹ but failed to consider the lines of evidence involved in a risk assessment. She acknowledged “*in vitro*, animal studies and epidemiological or human studies all are encompassed in the science of toxicology and toxicological research,”¹⁰⁰ but ignored animal and *in vitro* studies:

There’s already a lot of evidence in the epidemiological studies in the human studies that I did not spend a large amount of time in the scientific research looking at the animal studies or the *in vitro* studies, which are useful as we were talking about earlier, but for causation assessment analyses, you know, the human studies are what primarily -- what I emphasized in my report.¹⁰¹

Additionally, while her report contains an entire section on Risk Assessment and discusses the National Research Council’s (“NRC”)¹⁰² risk assessment methodology,¹⁰³ Dr. Tuttle admits she is only “vaguely” familiar with NRC’s risk

⁹⁹ Tuttle Report at 1; *Id.* App. A.

¹⁰⁰ Tuttle Dep. at 387:17-20.

¹⁰¹ *Id.* at 393:7-16.

¹⁰² The National Research Council is the principal operating agency of the National Academies of Sciences, Engineering and Medicine.

¹⁰³ See Tuttle Report at 9-12, one and one-half pages of which is lifted from Dr. Kind’s prior materials. The overt plagiarism of Dr. Kind’s report may explain why Dr. Tuttle was not familiar with the NRC risk assessment methodology.

assessment methodology. She was further unable to state whether the NRC's risk assessment methodology is one a toxicologist might use to perform a risk assessment.¹⁰⁴ This alone renders Dr. Tuttle's opinions unreliable.¹⁰⁵ In contrast, Dr. Plunkett, one of plaintiffs' expert toxicologists whose risk assessment methodology Dr. Tuttle criticizes, explicitly addresses the NRC methodology in both her report and deposition.¹⁰⁶ Dr. Tuttle's lack of knowledge of relevant toxicology methodology renders her opinion unreliable, as revealed by the following examples:

a. Hazard Assessment

Despite asserting she is trained to perform hazard assessments and has performed them in the past,¹⁰⁷ Dr. Tuttle could not identify any appropriate hazard assessment methodology, stating "I'd have to go look at the regulations to see what is put forth in those regulations regarding the methodologies for hazard assessment – I can't just speak to it generally."¹⁰⁸ Moreover, Dr. Tuttle has no "personal view"

¹⁰⁴ Tuttle Dep. at 59:18-61:4.

¹⁰⁵ *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999) (expert testimony excluded where expert does not use methodology that expert acknowledges is the "preferable methodology"); *see also Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 560 (W.D. Pa. 2003).

¹⁰⁶ Nov. 16, 2018 Expert Report of Laura M. Plunkett, Ph.D., DABT at 7-8, attached as **Exhibit T**; Dec. 19, 2018 Deposition of Laura Plunkett, Ph.D., DABT at 76:2-15, attached as **Exhibit U**. Dr. Tuttle includes the Dr. Plunkett's Expert Report and Deposition on her Materials Reviewed and Relied Upon list. Tuttle Report at 2.

¹⁰⁷ *See* Tuttle Dep. at 58:2-6, 59:15-17.

¹⁰⁸ *Id.* at 57:16-59:14.

or definition for “hazard assessment.”¹⁰⁹ Instead, she testified she would refer to regulatory agencies rather than her own knowledge base.¹¹⁰

b. Cytotoxicity

When asked to define cytotoxicity, Dr. Tuttle demurred, stating “I’m not sure that I can define it very clearly and scientifically.”¹¹¹ This, too, is a term addressed in Dr. Plunkett’s report¹¹² as a cytotoxin, refers to a substance that is toxic to cells.¹¹³

c. Reactive Oxygen Species

Dr. Tuttle’s report includes more than five pages on the concepts of carcinogenicity and genotoxicity.¹¹⁴ Yet, she makes no mention of reactive oxygen species (“ROS”), a biological concept significantly relevant to this case and addressed in the toxicology and biologic literature as it increases the risk of DNA mutations and contributes to the carcinogenesis process.¹¹⁵ When pressed, Dr. Tuttle

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.* at 339:5-340:11; 344:2-14.

¹¹² For instance, “[t]he toxicity potential of talc has been shown to be affected by the route of exposure, with more significant toxicity linked to penetration of small talc particles into tissues and triggering of cytotoxic responses at the local site of tissue interactions (EPA, 1992). Plunkett Report at p. 27.

¹¹³ See “cytotoxic.” Merriam-Webster.com. 2019. <https://www.merriam-webster.com/dictionary/cytotoxic>.

¹¹⁴ Tuttle Report at 12-17.

¹¹⁵ Klaassen (2013).

could explain the term “reactive oxygen species” and could not answer basic questions regarding whether ROS are significant to the carcinogenic process.¹¹⁶

In contrast to Dr. Tuttle, ROS is discussed by all of the PSC’s toxicology experts, Drs. Carson, Zelikoff and Plunkett, whom Dr. Tuttle criticizes, and addressed by numerous other experts in varying disciplines of medicine and science. Because ROS is implicated in cellular activity during a variety of inflammatory responses, and is discussed in the literature as a biologically plausible mechanism for talcum powders’ carcinogenicity, the omission of this discussion again raises doubt regarding the reliability of Dr. Tuttle’s expressed opinions.

d. Scientific Process

It is generally recognized that scientists evaluating the same data can reach different conclusions regarding a given question. In fact, courts reviewing causation opinions under Bradford Hill specifically recognize this concept.¹¹⁷ Dr. Tuttle, however, disagrees with this generally accepted view. It is her opinion that the scientific process is exacting and sets forth a mathematical or engineering-like

¹¹⁶ Tuttle Dep. at 324:4-21.

¹¹⁷ *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1307 (N.D. Fla. 2018) (“Determining whether an association is causal is a matter of scientific judgment, and scientists reliably applying the Bradford Hill factors may reasonably come to different conclusions about whether a causal inference may be drawn”) (citing *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 18 (1st Cir. 2011)); see also *Omnibus Brief* at Section I(A).

approach: “[I]f scientists are looking at the same body of science and applying the same methodology, they should arrive at the same conclusions.”¹¹⁸

e. Clearing of Foreign Particles

Dr. Tuttle was unable to explain whether the ovaries have the ability to clear foreign particles, indicating this was outside her area of research and not something she inquired into for this litigation.¹¹⁹ At best, she could only articulate: “generally speaking, and as I said, I don’t address that specifically in my report, but the human body has – has many defense mechanisms for removing materials from – from its – from the body.”¹²⁰ Dr. Tuttle similarly was unable to answer whether the respiratory system had the ability to clear foreign particles and clarified that this is not something she addresses in her report.¹²¹ Despite her inability to speak to these concepts, the body’s defense mechanisms are included in her report.¹²² This is clearly information added by someone other than Dr. Tuttle.

¹¹⁸ Tuttle Dep. at 122:23-123:2. *See also id.* at 272:1-7 (“when you look at a body of science and you apply a certain methodology, there -- your conclusions or what the science shows should be the same because the body of science is not changing between individual scientists”).

¹¹⁹ *Id.* at 138:2-141:3

¹²⁰ *Id.* at 140:16-20.

¹²¹ *Id.* at 140:4-20.

¹²² Tuttle Report at 33.

Dr. Tuttle also lacked familiarity with and failed to explain a number of other scientific terms and concepts necessary to render opinions on toxicological issues in this case, such as “hygienic talc use”¹²³ and “normal and intended use.”¹²⁴

The ability of an expert to provide reliable testimony goes well beyond their ability to conduct research. *See Calhoun*, 350 F.3d at 322 (“more specific knowledge is required to provide more specific opinions”); *Elcock*, 233 F.3d at 741 (“at a minimum, a proffered expert witness must possess skill or knowledge greater than the average layman”). Because Dr. Tuttle is unfamiliar with and cannot explain basic terms and concepts necessary to render opinions on key scientific issues in this case, her opinions are not reliable and should be excluded.

¹²³ Dr. Tuttle could not articulate what is meant by “hygienic talc use.” Tuttle Dep. at 249:17-250:15. This is despite the fact that Dr. Tuttle notes in her report that “I have been retained in this case as an expert in Toxicology and Industrial Hygiene,” and her report cites the results of a study regarding the association of hygienic use of talcum powder products and ovarian cancer. Tuttle Report at 1; *id.* at 23 (“[t]he author found no association between the hygienic use of talcum products and ovarian cancer”) (*citing* Langseth and Kjaerheim 2004).

¹²⁴ In her report, Dr. Tuttle opines the levels of fragrance chemicals and additives through the “normal use” of J&J’s talcum powder products would not cause adverse health effects. Tuttle Report at 67. However, at deposition, she was unfamiliar with the phrase “intended or normal use” of talcum powder products and stated that she “didn’t look for that phrase in [her] assessment of the scientific literature.” Tuttle Dep. at 344:15-345:17.

3. Dr. Tuttle Did Not Employ Reliable Methodology on Biological Plausibility

Dr. Tuttle also failed to employ appropriate and accepted scientific methodologies in formulating her opinions regarding biological plausibility. In this regard she did not conduct a qualitative analysis, failed to provide full information regarding what data she considered, and offered no explanation as to why she considered or failed to consider specific data.

Dr. Tuttle agrees that a weight-of-the-evidence approach should be conducted and claims that she “assessed the body of science as a whole.”¹²⁵ Despite this claim, her report and deposition reveals that she did no such thing. Instead she cherry-picked evidence that supports her opinions and discarded other evidence that did not. Dr. Tuttle’s testimony confirms she failed to assess, and in fact utterly ignored, relevant literature on biological plausibility.¹²⁶

¹²⁵ Tuttle Dep. at 119:10-23; *see also id.* at 121:10-19.

¹²⁶ *Id.* at 386:18-393:16 (did not consider animal and in vitro studies); *See also, id.* at 105:23-106:5 (did not consider Taher 2018, meta-analyses); 183:9-184:3 (did not consider Egli 1961, migration); 190:8-18 (did not consider Henderson 1971, migration); 391:7-21 (did not consider Shim and Radic, cited by Plunkett); 394:23-395:9 (did not consider Beck 1987, cited by Plunkett).

Although Dr. Tuttle had the resources to properly evaluate the evidence relied upon by plaintiffs' experts before reaching her opinions on biological plausibility,¹²⁷ she inexplicably chose not to review the totality of the evidence. Her failure to do so confirms a *post hoc* style of scientific evaluation. Rather than employing a reliable scientific methodology, Dr. Tuttle instead first referred to other experts' work and opinions, then looked to the scientific literature to generate the conclusion she already had:

Q. But do you feel comfortable discussing the migration theory within the boundaries of your expertise as you view -- as you view your expertise in this case?

A. Well, as I said, I reviewed the scientific literature regarding the migration theory and whether there's any scientific evidence to support the perineal application of talcum powder can reach the ovaries –

Q. Understood.

A. -- and found no scientific evidence to support that.

And as far as my training and expertise, I am -- you know, I review those types of studies as part of my ongoing work as a toxicologist. I'm not a gynecologist, so as I said, there are others involved that get into this in more detail than I do, and I would have to refer to their work and the data that they use in what they provide, but ultimately, I would look at the scientific literature and generate my own conclusions.¹²⁸

¹²⁷ Dr. Tuttle testified a CTEH information specialist, two toxicologists, and additional administrative staff assisted in generating her report. *Id.* at 96:12-100:10. Particularly, the information specialist – a health scientist – assisted Dr. Tuttle with literature searches. *Id.* at 63:3-13.

¹²⁸ *Id.* at 130:14-131:14.

Such selective review of the evidence renders Dr. Tuttle's methodology on biological plausibility unreliable *ipse dixit*.¹²⁹

a. Dr. Tuttle's *Ipse Dixit* Conclusory Opinions on Migration

In her report, Dr. Tuttle summarizes her "plausibility" argument by suggesting that "the plausibility of a relationship between talc exposure and ovarian cancer relies solely on the proximity of talc particles to the ovaries, and the proposed migration to the ovaries," and "the lack of evidence of talc effect on the reproductive

¹²⁹ *In re Seroquel Products Liability Litigation*, 2009 WL 3806434, at *5 ("A scientist who has a formed opinion as to the answer he is going to find before he even begins his research may be less objective than he needs to be in order to produce reliable scientific results." (citing *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985))); *see also In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 26 F. Supp. 3d at 461; *Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303 (6th Cir. 1997) (stressing that the court should consider litigation motivation in assessing the reliability of the expert opinion); *Lake Michigan Contractors, Inc. v. Manitowoc Co.*, 225 F. Supp. 2d 791, 803 (W.D. Mich. 2002) (An expert who "starts with his conclusion ... and then works backward for reasons to explain this conclusion without focusing on the specific facts and circumstances of the case" does not display the reliability that Daubert demands); *Munoz v. Orr*, 200 F.3d 291, 301 (5th Cir. 2000) (affirming exclusion of expert who "began his analysis with the assumption [plaintiff sought to prove]" and holding that this was "an indicator that he lacked the necessary objectivity to make his analyses credible"); *United States v. Fleet Mgmt. Ltd.*, No. CRIM.A. 07-279, 2008 WL 1924250, at *6 (E.D. Pa. Apr. 29, 2008) (excluding industry expert where expert "approached his investigation with a particular conclusion in mind ... and, without using any clearly-defined methodology, much less any intellectually rigorous analysis, he concluded that select facts and data could be interpreted to support that conclusion"). *In re Rezulin Products Liability Litigation*, 369 F. Supp. 2d at 425 ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.").

organs between the ovaries and genital area is an argument against this.”¹³⁰ Having framed her plausibility opinion in this manner, *i.e.*, resting solely on the validity of what she deems the “migration theory,” Dr. Tuttle repeatedly states there is “no scientific evidence” for migration. She reiterates this position throughout the deposition – approximately 30 times – oftentimes in total disregard to the topic or nature of the question asked.¹³¹ Dr. Tuttle’s empty assertion is a reminder that simply saying something does not make it so.¹³² Again it bears restating that biologic plausibility does not require “proof of mechanism,” but rather, it requires only an assessment of the biologic evidence to see whether it “makes sense” that the association that is seen is indeed causal.

Indeed, Dr. Tuttle’s “no evidence” position is undermined by her selective reference to one sentence in the IARC Monograph 93, which states “the evidence of

¹³⁰ Tuttle Report at 30.

¹³¹ Tuttle Dep. at 88:23-89:3; 110:2-21; 111:6-10; 112:10-16; 113:11-21; 114:4-9; 116:3-10; 117:15-17; 119:6-9; 120:8-12; 123:15-18; 126:4-9; 130:19-23; 136:20-137:4; 139:10-14; 186:8-11; 195:21-196:1; 212:21-213:3; 229:10-17; 230:8-11; 233:18-22; 239:2-6; 241:13-18; 244:12-20; 260:15-20; 303:13-22; 304:22-305:5; 332:9-17; 333:12-18.

¹³² *Oddi*, 234 F.3d at 158 (holding that an expert's *ipse dixit* does not withstand *Daubert's* scrutiny); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 595 (D.N.J. 2002) citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997) (“nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”).

retrograde transport is weak.”¹³³ On its face, this sentence conflicts with Dr. Tuttle’s own opinion that there is *no* scientific evidence. When questioned at her deposition concerning the basis for her migration opinion, Dr. Tuttle admitted that she did not read the scientific literature referenced in the IARC monograph on migration nor did she review the relevant body of migration literature to arrive at her opinions on biological plausibility.¹³⁴

Dr. Tuttle struggled and failed to provide tangible support for her opinions regarding migration.¹³⁵ Dr. Tuttle failed to explain why talc may be found in the ovaries if it did not migrate there, stating it was irrelevant to her review of the scientific literature¹³⁶ and was not her specific research objective: “looking at the migration theory rather than just the presence of talc in the ovaries”.¹³⁷ Just as

¹³³ International Agency for Research on Cancer. "Titanium dioxide." *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 93: Carbon Black, Titanium Dioxide, and Talc* (2010): p. 411, attached as **Exhibit V**.

¹³⁴ Tuttle Dep. at 180:22-196:23; *id.* at 158:1-159:14 (did not review Egli); 159:23-164:2 (did not review Henderson 1971); 164:5-165:22 (did not review Venter); 167:20-170:6 (did not review Henderson 1986); 170:9-172:3 (did not review Kissler); 172:5-174:8 (did not review Sjosten 2004); 174:12-180:20 (did not review McDonald).

¹³⁵ *Id.* at 129:17-135:5, 210:14-216:7.

¹³⁶ *Id.* at 215:8-14.

¹³⁷ *Id.* at 210:1-8.

concerning, Dr. Tuttle could not give a definition of “retrograde transport,”¹³⁸ an important medical concept relevant to the migration theory.

Dr. Tuttle should not be permitted to express her *ipse dixit* opinion on migration or criticize other experts’ opinions on migration, as her opinions here lack the requisite methodological foundation.

b. Dr. Tuttle’s Conclusory *Ipse Dixit* Opinions on Inflammation and Carcinogenesis

Dr. Tuttle also offers conclusory mechanistic opinions related to inflammation and carcinogenesis. As with migration, Dr. Tuttle ignores scientific evidence on inflammation and carcinogenesis and fails to apply sound scientific methodology to the facts and science to reach her opinions.

After joining CTEH in 2013, Dr. Tuttle co-authored an article (“Nony 2014”) with other CTEH toxicologists that discussed the mechanism of toxicity and inflammatory response of foreign particles and resulting carcinogenesis (*i.e.* tumor growth).¹³⁹ Importantly, one of the plaintiffs’ primary contentions here regarding biological plausibility is that talcum powder applied to the perineum can migrate up the genital tract to the ovaries and initiate an inflammatory response, which can lead to carcinogenesis. The latter two stages of this process are subjects touched upon in

¹³⁸ *Id.* at 151:17-23 (“I don’t have a specific definition”).

¹³⁹ Tuttle Dep., Ex. 30, Nony, P., K. Scribner, and T. Hesterberg. "Synthetic Vitreous Fibers." (2014): 448-453, attached as **Exhibit W**.

her 2014 article referenced earlier. In an effort to question Dr. Tuttle on the mechanistic issues, she was shown the FDA's following position on migration and foreign body inflammatory response:

...plausible that perineal talc (and other particulate) that reaches the endometrial cavity, fallopian tubes, ovaries and peritoneum, may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers.¹⁴⁰

When asked if the FDA description is similar to the type of foreign body reaction and inflammatory response in her article, Dr. Tuttle had absolutely no idea.¹⁴¹ She later admitted: "I have not, I think I said earlier, brushed up on my understanding of the mechanistic toxicology or the mechanisms revolving inflammation in regards to my report or the assessment of talcum powder and ovarian cancer."¹⁴² Indeed, she failed to consider important scientific evidence on inflammation and carcinogenesis.¹⁴³ Dr. Tuttle exhibited a wholly deficient understanding of relevant inflammatory processes, deflecting all questions on the issue by stating "there are others who get more into the mechanisms and pathways

¹⁴⁰ FDA Response Letter (April 1, 2014) at 5.

¹⁴¹ Tuttle Dep. at 326:7-327:10.

¹⁴² *Id.* at 330:8-13. *See also id.* at 334:14-335:4, 336:16-337:22 (testifying that she did not look deeply into genetic mechanisms of inflammation, or the inflammatory process – deferring to others, who "get more in depth as far as mechanisms than I do.")

¹⁴³ Tuttle Report at 72-85 (did not consider Shukla et al. 2009 or Buz'zard et al. 2007).

regarding inflammation than I do.”¹⁴⁴ Dr. Tuttle is also without the requisite specialized expertise and knowledge to provide reliable opinions on this topic of biological plausible mechanisms.¹⁴⁵

For the reasons stated above, and in order to avoid confusing the trier of fact, Dr. Tuttle’s unqualified and unreliable opinions should be excluded in full.

C. DR. MOORE’S OPINIONS SHOULD BE EXCLUDED

1. Dr. Moore is Not Qualified to Critique Experts in Fields Other Than Toxicology

Dr. Moore is unqualified to render an expert opinion on the toxicological properties of talc or ovarian cancer because she has no experience, education, or training on either topic. Her general status as a toxicologist is not enough.

While Dr. Moore served as a toxicologist for ten years, she has no background, education or training to provide opinions outside that realm. As she admitted in her deposition, she has no laboratory experience with talcum powder, including *in vitro* studies or analysis of talcum powder by X-ray diffraction (XRD), polarized light microscopy (PLM), or transmission electron microscopy (TEM):

Q. Have you ever done any testing involving talc?

¹⁴⁴ Tuttle Dep. at 314:8-319:20.

¹⁴⁵ *Calhoun*, 350 F.3d at 322 (“more specific knowledge is required to provide more specific opinions”); *Elcock*, 233 F.3d at 741 (“at a minimum, a proffered expert witness must possess skill or knowledge greater than the average layman”).

A. So by testing, you mean –

Q. Lab tests.

A. Laboratory-based testing?

Q. Yes.

A. No, I have not.

Q. And that would include cell testing, microscopic analysis, any -- any type of testing. I just want to make sure I'm not missing anything here.

A. I have not tested talc in a laboratory setting.¹⁴⁶

Dr. Moore's lack of laboratory experience also extends to ovarian cancer.¹⁴⁷

Dr. Moore seeks to rebut the expert testimony and research of Dr. Ghassan Saed, a cancer biologist.¹⁴⁸ Dr. Moore not only lacks training, education, or experience in such areas, she also has no understanding of what Dr. Saed's qualifications are or the breadth of methodology of research he conducted.¹⁴⁹ Unlike Dr. Moore, Dr. Saed is a cancer researcher and has published in the areas of inflammation and ovarian cancer throughout his career.¹⁵⁰ The work of Dr. Saed's lab is focused on research related to cancer biology specifically ovarian cancer and

¹⁴⁶ Moore Dep. at 198:10-22.

¹⁴⁷ *Id.* at 186:17-22.

¹⁴⁸ Moore Report at 93-96.

¹⁴⁹ Moore Dep. at 161:3-162:21, 186:12-16.

¹⁵⁰ See Curriculum Vitae of Ghassan Saed, PhD, attached as **Exhibit X**.

other inflammatory conditions such as pelvic adhesions. By contrast, Dr. Moore has not conducted any original research involving *in vitro* studies.¹⁵¹ She does not have any expertise or training in cancer biology to address Dr. Saed's methodology.¹⁵² Dr. Moore is not qualified to offer criticisms of Dr. Saed's research involving talcum powder, inflammation, and the biology of ovarian cancer.

The same is true of Dr. Moore's attempt to criticize the opinions of Dr. William Longo.¹⁵³ Dr. Longo has a Ph.D in a Material Science and Engineering,¹⁵⁴ has conducted analysis of bulk materials for more than 30 years, published on the methodology for analyzing bulk samples for fibrous materials, and has been involved in the drafting and adopting of testing methodology that is generally accepted in the industry. Dr. Moore has never tested talcum powder or any other bulk sample for the presence of fibrous material such as asbestos or fibrous talc.¹⁵⁵ Dr. Moore has no training, expertise or experience in the area of the analysis of samples for the presence of fibrous material.¹⁵⁶ As a result, Dr. Moore's criticisms of Dr. Longo's testing methodology should be excluded.

¹⁵¹ Moore Dep. at 186:17-19.

¹⁵² *Id.* at 186:23-187:4.

¹⁵³ Moore Report at 44-49.

¹⁵⁴ See Curriculum Vitae of William Longo, PhD, attached as **Exhibit Y**.

¹⁵⁵ Moore Dep. at 198:5-22.

¹⁵⁶ Moore Report at 44.

2. Dr. Moore Is Not Qualified to Opine on the Presence of Fibrous Talc

Dr. Moore also should be prohibited from testifying about the presence or absence of fibrous talc particles within the J&J talcum powder products. Though her report speaks to the mineralogy of talc,¹⁵⁷ Moore testifies that she defers to other experts as to the presence of fibrous talc within the finished product:

Q. Do you know what fibrous talc is?

A. I do.

Q. Is fibrous talc found in baby powder?

A. So I -- to be honest, I evaluated the powder that existed in the bottle, and probably better -- one of the other experts in this matter would be better accustomed or better versed to tell you the -- the makeup of the powder that was in the bottles that I evaluated.¹⁵⁸

As Dr. Moore acknowledged, the portions of her report that pertain to composition (including the presence of asbestos and fibrous talc) or testing of talcum

¹⁵⁷ *Id.* at 19.

¹⁵⁸ Moore Dep. at 284:15-25.

powder products lie outside the scope of her expertise and, therefore, any opinions in her report that purport to comment on those topics should be excluded.¹⁵⁹

3. Dr. Moore’s “Cherry-Picking” Methodology is Unreliable

Dr. Moore’s methodology also is unreliable because she only considered evidence that supports her litigation report. Dr. Moore summarized her primary opinion in this case thusly: “[s]cientific literature does not support a causal relationship between perineal talc use and ovarian cancer.” The methodology she employed in reaching this opinion was “evaluat[ing] the scientific literature that was related to this issue.”¹⁶⁰

Unfortunately, Dr. Moore only evaluated the scientific literature she perceived as supportive of her opinions. Focusing on extremely limited evidence, or ignoring

¹⁵⁹ *Calhoun*, 350 F.3d at 322; *Elcock*, 233 F.3d at 741; *Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1056 (3d Cir. 1997); *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 397 F. App'x 797, 800 (3d Cir. 2010) (affirming exclusion of proffered expert testimony, in part because the witness “articulated no expertise in the field of aerodynamics or air flow”); *see D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. CIV.A. 03-1026 (MLC), 2006 WL 755984, at *3 (D.N.J. Mar. 20, 2006) (“If an expert’s area of expertise is adjacent to, but not actually encompassing, the subject matter of his testimony, he may be deemed unqualified.”).

¹⁶⁰ Moore Dep. at 40:9-22.

the totality of available relevant scientific proof, renders an expert opinion unreliable and scientifically unsound.¹⁶¹

Commonly referred to as a “weight of the evidence evaluation” or a “literature review,” courts emphasize that such studies are deemed sufficiently reliable only when carried out in a responsible fashion. “When a weight-of-the-evidence evaluation is conducted, all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.” *Magistrini*, 180 F. Supp. 2d at 602; *see also Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 472 (M.D.N.C. 2006) (internal citation omitted) (“[A] literature review can be an appropriate part of a method of determining general causation. However, a literature review must still be performed appropriately.”)

¹⁶¹ *In re Neurontin Mktg. & Sales Practices Litig.*, 04-CV-10739-PBS, 2011 WL 3852254, at *34 (D. Mass. Aug. 31, 2011), aff’d, 712 F.3d 21 (1st Cir. 2013) (excluding expert’s testimony where it was found that the expert “reache[d] his opinion by first identifying his conclusion . . . and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion.” (citing *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 524 F. Supp. 2d at 1176); *Yates*, 113 F. Supp. 3d at 858; *see also In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 26 F. Supp. 3d 449 (finding expert’s opinion not reliable or scientifically sound because the expert failed to account adequately for contrary evidence (citing *In re Avandia Mktg.*, No. 2007-MD-1871, 2011 U.S. Dist. LEXIS 479, at *9 (E.D. Pa. 2011))).

“Result-driven analysis, or cherry-picking, undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II)* MDL 2502, 892 F.3d 624, 634 (4th Cir. 2018). Courts consistently exclude expert testimony that “cherry-picks” relevant data. *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017).¹⁶² “Conclusions drawn from such unreliable application are themselves questionable.” *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d at 798.

Conspicuously absent from Dr. Moore’s report was any reference to the December 2018 report of Health Canada (the governmental agency responsible for Canadian public health) that specifically contradicted Dr. Moore’s finding that “scientific literature does not support a causal relationship between perineal talc use and ovarian cancer.”

Q. It's on the screen right there. It says: "Scientific literature does not support a causal relationship between perineal talc use and ovarian cancer." That's what you said in February of 2019, correct?

¹⁶² *E.E.O.C. v. Freeman*, 778 F.3d 463, 469 (4th Cir. 2015) (citing *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Sec. (USA) LLC*, 752 F.3d 82, 92 (1st Cir. 2014)); *Greater New Orleans Fair Hous. Action Ctr. v. U.S. Dep't of Hous. & Urban Dev.*, 639 F.3d 1078, 1086 (D.C. Cir. 2011); *Barber v. United Airlines, Inc.*, 17 F. App'x 433, 437 (7th Cir. 2001); *Fail-Safe, L.L.C. v. A.O. Smith Corp.*, 744 F. Supp. 2d 870, 891 (E.D. Wis. 2010); *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 524 F. Supp. 2d at 1176–77.

A. Correct.

Q. Exhibit 7, Health Canada came out in December 2018, and you said you were aware of it –

A. That is correct.

Q. -- shortly after it came out and before you wrote your report, right?

A. While I was writing my report, yes.

Q. Okay. So Health Canada says: "The meta analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. Further, available data are indicative of a causal effect." Did I read that correct?

A. You did read that correctly.¹⁶³

Dr. Moore attempts to explain away her omission of the Health Canada report by emphasizing “[i]t’s a draft. ... So it’s unclear what the final assessment will say.”¹⁶⁴ Within the publicly-released document, however, are scores of peer-reviewed references relied upon by the Canadian government in arriving at its conclusions,¹⁶⁵ some of which are conveniently missing from Moore’s report and her conclusions.

¹⁶³ Moore Dep. at 170:17-171:16.

¹⁶⁴ *Id.* at 173:16-24.

¹⁶⁵ See Health Canada Draft Screening Assessment.

At best, Dr. Moore overlooked a key piece of scientific evidence relating to the plausibility of talcum powder causing ovarian cancer. At worst, she is knowingly ignoring any evidence that contradicts her opinions. Either way, her testimony regarding causation unreliable and should be excluded.

Dr. Moore criticizes plaintiffs' experts, Drs. Carson, Crowley, Plunkett, and Zelikoff regarding their opinion that talc induces inflammation and that inflammation "extends biological plausibility to ovarian carcinogenesis."¹⁶⁶ Dr. Moore, quick to criticize, failed to consider one of the many primary references upon which the plaintiffs' experts relied for their opinion that talcum powder induces inflammation and causes biologic changes consistent with carcinogenicity.¹⁶⁷

Finally, despite criticizing the opinions of Drs. Plunkett and Crowley, Dr. Moore could not testify that she completely reviewed their reports.¹⁶⁸

The Supreme Court has cautioned against allowing experts too much leeway in reaching conclusions in "weight of the evidence" analyses:

Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

¹⁶⁶ Moore Report at 35.

¹⁶⁷ Shukla (2009).

¹⁶⁸ Moore Dep. at 302:10-303:2.

General Elec. Co., 522 U.S. at 146. Dr. Moore's *ipse dixit* is what we are left with when she is continuously confronted with scientific evidence that contradicts her conclusions. For this reason, her opinions are unreliable and should be excluded.

V. CONCLUSION

For the foregoing reasons, plaintiffs request that the opinions of J&J's toxicology experts Brooke T. Mossman, M.S., Ph.D., Kelly S. Tuttle, Ph.D., and H. Nadia Moore, Ph.D. be excluded.

Respectfully submitted,

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